A portion of this document (page 28) has been claimed confidential. Requests for this document will be processed under the Freedom of Information Act (FOIA) and EPA's public information regulation at 40 CFR Part 2, subpart B.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Chemical: Malathion
Chemical No: 057701
DP Barcode: D268854

MEMORANDUM: EFED's Response to Docket Comment

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The Environmental Fate and Effects Division (EFED) has responded to public comments received related to the draft risk assessment released for malathion. The EFED malathion risk assessment team reviewed all the comments received in the docket and responded to all criticisms of the risk assessment in the areas of ecological risks and water resources.

In some instances comments identified errors or portions of the risk assessment needing further clarification. Errors and clarifications are noted in the following responses. Several comments were criticisms of EFED's policies and procedures for estimating and communicating risks and not directly related to the risk assessment. To address these concerns the team responded with justifications for the policies and procedures used.

Changes made to the risk assessment have not significantly altered EFED's conclusions regarding malathion. EFED's primary issues related to malathion risk are:

- Malathion is toxic to aquatic organisms at concentrations which have been monitored or are predicted to occur as a result of registered uses.
- Malathion has high potential to drift off target from aerial ULV applications.
- Urban malathion uses result in increased run-off and surface water body concentrations.
- Malathion is hazardous to reproductive success of certain species of birds and mammals at higher registered use rates.

Malathion also possesses some properties which reduce risks associated with its use. Malathion's rapid degradation on soils with high microbial activity and many water bodies results in reduced environmental exposures relative to other organophosphate insecticides. Malathion also provides greater selective toxicity relative to many other organophosphate insecticides.

Attached below are public comments and EFED's responses.

Response to "Comments from Cheminova A/S on EPA's Preliminary Risk Assessment for Malathion" July 10, 2000, submitted by Jellinek, Schwartz and Connolly, Inc.

The Cheminova comments are numbered for reference purposes. The submitted comments were not numbered.

1. **Cheminova comment:** Jellinek, Schwartz, and Connolly (JS&C) (page 11) requests that HED and EFED note in their RED chapters any use rates included in the risk assessments that are not supported by residue data.

EFED response: Whenever possible, EFED used rates included in the SMART Meeting book provided by the registrant. Where uses were not specified in the field practices / test rates section of the book (mostly non-food crop uses) the maximum rates found on existing labels were employed. Rates that will no longer be supported will be changed upon reregistration.

2. **Cheminova comment:** JS&C (page 18) suggest that the malathion and malaoxon drinking water concentration estimates are unreasonably high and a more extensive review of existing monitoring data should be conducted to generate a more refined estimate.

EFED response: As explained in the preliminary risk assessment, EFED uses a tiered system to generate estimates of pesticides in drinking water. First-tier assessments are intended to estimate conservative concentrations to be used in exposure assessments. If first-tier screening level concentrations result in unacceptably high exposures, more refined and resource-intensive exposure assessments are generated. For malathion, the drinking water exposure assessment used did not result in unacceptable dietary residues, so a more refined assessment was not conducted and the values in the risk assessment were described as "highly conservative". Malathion monitoing data in ground and surface water was reviewed, however, a more extensive review of malathion, malaoxon, and other degradates and impurities is not required at this time.

3. **Cheminova comment:** JS&C (page 19) questions the use of groundwater monitoring data and the SCIGROW model in generating first tier groundwater concentrations for malathion. JS&C criticizes the fact that monitoring data with higher levels of malathion were used instead of the SCIGROW model in the screening-level groundwater assessment. JS&C also expresses concerns over the quality of the monitoring data that was collected in Westmoreland County, VA.

EFED response: As explained in the water resource assessment the SCIGROW model was run for malathion to generate a first-tier estimate of malathion groundwater concentrations in a vulnerable setting. The SCIGROW result was a concentration of 0.142 ppb. However, a review of EPA's Pesticides in Ground Water Database (EPA 1992) showed measured concentrations

exceeding the SCIGROW result, suggesting that SCIGROW may not produce a conservative estimate of malathion groundwater concentrations. Therefore, for the first-tier assessment, data from the well with the highest measured groundwater concentration (from Westmoreland County, VA) was used as the assessment concentration. The highest concentration reported from the well (6.17 ppb) was not used. Instead, a lower concentration (3.1 ppb) was used as a more accurate estimate of the measured concentration (appendix 2 of the risk assessment and EPA 1998). Because the groundwater assessment value was lower than the surface water assessment screening concentration, the Westmoreland County groundwater monitoring data was not used for the dietary exposure assessment. Therefore, closer scrutiny of malathion groundwater concentrations are not required at this time.

4. **Cheminova comment:** JS&C (page 19) questions the groundwater malaoxon concentration used in the water resources assessment. JS&C state no justification was made in choosing the malaoxon groundwater concentration.

EFED response: The risk assessment used a malaoxon concentration of 3.1 ppb, a value equal to that of the malathion groundwater concentration. In regard to malaoxon and water contamination, the risk assessment states that few environmental fate parameters of malaoxon are known in order to generate model estimates of its concentration. Because of this lack of information, conservative assumptions were made in order to estimate environmental concentrations. The risk assessment states the assumption was made that malaoxon concentrations in groundwater would not likely exceed malathion's concentration. Therefore the upper-bound monitored malathion concentration was used as a conservative estimate of malaoxon concentration in groundwater. This was a highly conservative assumption because under most circumstances malaoxon production does not exceed 10% of the applied malathion. The resulting exposure to the conservative estimate of malaoxon concentration did not exceed dietary levels of concern and more resource intensive refinement procedures were not required.

5. **Cheminova comment:** JS&C (page 24) states that the Westmoreland County measurements of malathion in groundwater are used as a justification for further studies defining the environmental behavior of malathion. JS&C believes these data are not adequate to justify additional studies that are not required for other chemicals.

EFED response: JS&C's statement is a based on a selective quote from the risk assessment. Although the context is correct, it is important to note that all the malathion detections in groundwater [including a detection in California exceeding the SCIGROW value (see the risk assessment and EPA 1992)] are only one of the reasons used to justify the need for further studies defining its persistence under unfavorable conditions. The other reasons used to justify the need for additional studies are high urban surface water measurements made by USDA and USGS and reports of increased persistence on low moisture, low organic content soils and anthropogenic surfaces reported in the scientific literature and USDA reports. Given the wide variety of

agricultural, home and garden, and public health uses of malathion, it is likely that the chemical will encounter environmental conditions which are unfavorable for degradation.

6. **Cheminova comment:** JS&C (page 25) state that incorrect fate parameters were used to model environmental concentrations of malaoxon. They state the 3x factor applied to the malaoxon soil half-life [derived from the open literature study: Paschal and Neville (1976)] is not required because the authors state abiotic degradation is the most important mechanism. JS&C implies that abiotic degradation of malaoxon in soils is less variable than biotic degradation. JS&C also state that the aquatic half-life of malaoxon used for modeling should be replaced with a value derived from soil metabolism.

EFED response: EFED recognizes that it was necessary to make assumptions about the environmental persistence of malaoxon. The risk assessment states that assumptions were required because adequate data do not exist on malaoxon. It is also stated that guideline studies on the environmental fate parameters of malaoxon would be very useful for more refined estimates. Under the present circumstances, with no acceptable data on aerobic soil metabolism and no data on aerobic aquatic metabolism, EFED believes it is necessary to apply the 3x factor to the soil half-life and to make a conservative estimate of aquatic half-life based on malathion's behavior. If additional modeling was required, guideline study data on malaoxon would be necessary to better estimate environmental concentrations. However, the malathion + malaoxon concentration predicted by modeling with conservative input values did not exceed levels of concern.

7. **Cheminova comment:** JS&C (page 26) state that EPA should not use GENEEC or PRZM/EXAMS for estimating drinking water concentrations. JS&C states the farm pond scenario is overly concervative for this purpose.

EFED response: EFED's farm pond drinking water assessment modeling was used as a screening tool. EFED is open to consideration of well validated higher tier modeling. EFED recognizes the concerns regarding the use of the farm pond scenario and has implemented a scenario incorporating reservoirs considered to be vulnerable to pesticide runoff in the modeling assessment of drinking water. EFED conducted a comparison of contaminant predictions for the farm pond scenario and an index reservoir of larger surface area, volume, and drainage area for presentation to the July, 1998 SAP. Predicted concentrations of hypothetical uses of selected pesticides were higher in the index reservoir than in the farm pond when crop area factors were not considered. However, when crop area factors were incorporated in the assessment were presented to the SAP, predicted index reservoir concentrations were slightly lower (by a factor of 0.3 to 0.5) than farm pond predictions. Drinking water-based concerns, triggered by modeling results, typically lead to an evaluation of available water monitoring data.

EFED is currently moving towards a probabilistic approach for modeling that will enable

increased consideration of a parameter's distribution, where available data are of sufficient quantity and quality, in the calculation of EECs. Until such time that EFED adopts a probabilistic drinking water assessment, EFED will continue to employ the current approach.

8. **Cheminova comment:** JS&C (page 26) state that EFED should rely on monitoring data for estimating drinking water concentrations.

EFED response: EFED is open to the consideration of statistically representative, technically well conducted monitoring studies for use in exposure assessments. However, in instances when conservative screening model estimates do not result in concentrations exceeding levels of concern, these levels will be used in risk assessments.

9. **Cheminova comment:** JS&C (page 53) state that if open literature results are to be included, the studies should be fully evaluated, and include a discussion of the uncertainties associated with the studies. JS&C proposes that more weight should be given to registrant-submitted guideline studies than those from the open literature.

EFED response: EFED believes that peer-reviewed open literature provides a valuable source of data to characterize registrant-submitted guideline study results. Open literature studies can provide data under more conditions than are available from registrant-submitted studies. In many instances open literature results corroborate the registrant-submitted study results (e.g. hydrolysis rate with varying pH, photodegradation, and anaerobic aquatic metabolism). In some instances the open literature results help to place the registrant's results in context. For example, ten open literature references are provided on the soil half-life of malathion. The results and conditions of the studies provide a more detailed picture of the persistence of malathion and its relationship to environmental factors. When guideline study data were available, they were used with more weight than open literature references. Registrant-submitted studies were used quantitatively in the risk assessment while open literature data were used in qualitative comparisons to characterize registrant data. EFED believes that the quantitative use of registrant-submitted data addresses JS&C's concern over the relative weight of registrant data versus open literature data.

10. **Cheminova comment:** JS&C (page 54) believe an additional aerobic soil metabolism study on low moisture and low organic soil should not be required. JS&C states they are not aware of any precedent for requiring this study and two of the non-registrant-submitted studies used to justify the need for the additional study are flawed.

    JS&C (page 56) states the aerobic aquatic metabolism study conducted under alkaline conditions should be reclassified as acceptable and additional data under acidic conditions should not be required. JS&C states guidelines do not specify that aquatic metabolism studies need to be conducted at pHs that are not conducive to hydrolysis. JS&C also

questions the utility of the study's results, suggests the metabolites would be similar, suggests malathion is being held to a higher standard than other pesticides, and suggest that many surface water measurements indicate that malathion in surface water is not an issue.

JS&C (page 57) disagrees with the request for a non-guideline study on degradation on anthropogenic surfaces. JS&C suggests that it would be difficult to place the results of the study in context and malathion should not be more persistent than other pesticides on surfaces.

EFED response: EFED's requests for additional studies on malathion largely stem from measurements of malathion and malaoxon in urban surface water bodies. USDA and USGS monitoring data (cited in the risk assessment) suggest that malathion concentrations in water bodies receiving urban runoff are significantly higher than other run-off despite the fact that the majority of malathion usage occurs in non-urban settings. Targeted USDA studies show high levels of malathion and malaoxon in urban streams where malathion is used to control medfly infestations and low runoff levels in non-urban cotton growing areas where usage is approximately ten-times higher. Non-targeted USGS studies also show higher concentrations and more detections in urban streams as opposed to streams in rural or mixed-land use settings. This suggests that an inordinate amount of environmental risk is occurring as a result of urban malathion usage. A USDA/APHIS comment on the malathion risk assessment (7/10/2000) supports this position:

> "The factor implicated in nearly all fish kills is run-off in highly urbanized areas, where much of the watershed is composed of streets, sidewalks, and rooftops, all of which are impervious to water and which feed local streams or storm drains. Receiving ponds concentrate residues from throughout the watershed, depending on the amount of runoff and dilution volume. Thus, some Medfly programs in urban areas have resulted in fish kills, although these programs comprise less than 2% of the total malathion used." (Page 10)

Two of the three studies EFED requested help to address environmental differences between urban conditions and the agricultural conditions which are better represented by the registrant-submitted guideline studies. The aerobic soil metabolism study on low moisture and low organic soil is representative of many urban soils (particularly in the western US) and the persistence and fate of malathion on anthropogenic surfaces would provide data on malathion that would presumably be more available to runoff and oxidation to malaoxon. The third study would help to provide additional data on malathion persistence in water under conditions that are less conducive to degradation than those in the registrant-submitted study. Together, results from these studies would help to define why malathion and malaoxon occur more frequently in urban water bodies relative to non-urban surface water. EFED believes the results of the studies would be useful in making risk management decisions.

11. **Cheminova comment:** JS&C (page 57) disagrees with the request for data on the environmental fate of malaoxon. JS&C states that malathion is being held to a higher standard than other organophosphate pesticides, that malaoxon occurs only rarely in the environment and at low concentrations, and that additional fate studies would be expensive. JS&C suggest that instead of using fate data for malaoxon, estimation methods could be used.

EFED response: Targeted USDA monitoring studies measuring malaoxon runoff from cotton agriculture support JS&C's claim that malaoxon occurs only rarely in the environment. However, other targeted USDA studies in urban water bodies suggest that malaoxon can occur frequently and at high levels in urban settings where malathion is used in medfly control. Home and garden use of malathion and other urban uses of malathion would be expected to undergo the same transformations and transport processes as those measured with applications to control medfly and would thus be expected to result in malathion and malaoxon occurrences in urban streams. This theory is supported by the USGS NAWQA study data showing detections of malathion in approximately 20% if the samples collected from urban streams.

Malaoxon has also be documented to occur in public drinking water systems. Monitoring data of water entering and leaving a drinking water treatment facility in Florida suggest that malathion was converted to malaoxon in the water treatment process. Malathion was measured at the treatment facility intake on thirteen instances and no malaoxon detections were made. In the finished treated water, malaoxon was detected fourteen times and no malathion was detected. When OPP performs a cumulative exposure assessment for OPs it would be extremely useful to have hydrolysis data on malaoxon to understand the persistence of this chemical in the drinking water delivery system.

Malaoxon fate and transport studies are required to better understand the chemical's behavior in the areas where it is expected to occur most often: urban environments. Malaoxon could pose a threat to drinking water facilities located in watersheds composed partly of urban areas. In addition, malaoxon can be toxic to fish and other aquatic organisms which inhabit water derived from urban watersheds. Aerobic aquatic metabolism and hydrolysis data on malaoxon will help to define malaoxon persistence in surface water where malaoxon has been documented. If the registrant provides requested aerobic soil metabolism and anthropogenic surface data on malathion it would probably be unnecessary to provide aerobic soil metabolism data on malaoxon. Malathion studies' results would provide the necessary information on the production and decline on malaoxon under adverse conditions common in urban environments. Additionally, since environmental malaoxon appears to be most likely to occur in urban surface water a leaching/adsorption study is not as critical as an aerobic aquatic degradation study. Adsorption studies would not likely provide useful information on runoff from impermeable surfaces in urban environments.

12. **Cheminova comment:** JS&C (page 60) states that Cheminova believes that EFED should

rely on product chemistry and other data provided by the registrant to identify the occurrence and magnitude of impurities in technical malathion. They state that certain chemicals identified as impurities in malathion are not detected in Cheminova's analyses. They also state that a reference was not provided in the risk assessment for a list of reported impurities. JS&C provided a confidential attachment with additional information on the presence of impurities in malathion.

EFED response: The risk assessment has been corrected to include a reference for the impurities and their magnitudes stated to have been measured in technical malathion. EFED has modified the text in this portion of the risk assessment to suggest that current malathion formulations generally result in lower levels of impurities than in the past. To address comments made in JS&C's confidential attachment, EFED has responded in an attached confidential memorandum.

17. Cheminova comment: JS&C (page 61) states that the risk assessment provides an incomplete summary of the toxicity of potential impurities in malathion and that EFED should clarify that these concerns are not implicated by all possible impurities. They request that the toxicity and action associated with individual impurities and mixtures of impurities be stated to provide a more detailed discussion on impurities in the risk assessment. JS&C states that the risk assessment exaggerates toxicity issues related to impurities and EFED implies that malathion is routinely improperly stored.

EFED response: The EFED risk assessment includes a 2-page summary discussion of impurities and storage degradation products of malathion in the risk assessment. The discussion highlights what EFED believes are the most important risks associated with impurities and malathion storage stability:

1. "Some malathion ... impurities can potentiate malathion toxicity and also are toxic alone"

2. "the composition and toxicological properties of the technical product are affected by initial quality and storage conditions"

Several references cited in the risk assessment as well as the confidential attachment to JS&C submission support these statements. The risk assessment clearly states "several" organophosphate impurities potentiate malathion toxicity. It is not stated or implied that all potential impurities potentiate toxicity or are highly toxic themselves. A number of open literature papers provide detailed discussions of the actions and toxicity of potential malathion impurities. These references are cited in the risk assessment and in JS&C's comment letter and need not be included in the risk assessment.

EFED did not imply that malathion is routinely stored improperly by users. The risk assessment quotes results from open literature studies showing that the toxicity of malathion increases when it is stored improperly (under high temperatures). This merely identifies that poor storage

conditions will increase risks associated with malathion use. The registrant has conducted studies and determined that malathion is stable under conditions specified on product labels. EFED recommends that a statement on labels be included to warn users of increased toxicity as a result storing the malathion at high temperatures.

In response to JS&C's stated concern that EFED has exaggerated toxicity concerns associated with impurities in malathion, changes have been made in this portion the risk assessment. These changes reflect EFED's belief that malathion produced by Cheminova has reduced levels of impurities relative to older formulations and should therefore be of lower risk if properly stored. In addition, the acronym DEF for diethyl fumarate has been deleted as requested to avoid any confusion with tribufos, which uses the same acronym.

14. Cheminova comment: JS&C (page 61) states it sees no rationale for EFED making an issue of diethyl fumarate toxicity to fish because this compound is present as only a low-level impurity (<1 percent), and it shows only moderate toxicity to fish according to the data cited by EFED (LC50 = 4.5 ppm) (Bender 1969). Even with EFED's very conservative modeling procedures, diethyl fumarate concentrations in water will not approach this concentration.

EFED response: EFED did not use the data in any of its risk assessment conclusions. It was presented only as toxicity data. There is a statement in the RED regarding the low concentrations of these compounds that are expected in the environment and the fact that they are not close to the cited values:

> "Studies by Dr. Michael Bender at the University of Michigan (1969) and Virginia Institute of Marine Sciences (1976) showed that diethyl fumarate and 2 mercapto diethyl succinate were more toxic than the parent compound to fathead minnow and eastern mudminnows (see pages 71-72). However the percentage of these degradates in the environment is expected to be low enough(<10% of original parent) to prevent additional toxicity to fish."

15. Cheminova comment: JS&C states (page 62) that EFED uses conservative modeling practices to estimate malathion concentrations in surface water bodies and estimating aquatic risks. JS&C believe the 10-hectare field, 1-hectare pond are very rare in agriculture. JS&C also state that EFED uses very conservatively chosen model inputs such as aerobic soil metabolism. JS&C believes the aerobic soil metabolism input used in modeling was overly conservative and registrant-submitted laboratory and field dissipation data suggest that half life is significantly shorter. JS&C believes that the risk assessment should include aquatic concentrations based on less conservative assumptions.

EFED response: The EFED 1-hectare pond scenario models surface water contamination from

runoff and drift from a 10-hectare field to a 1-hectare (approximately 12,000 yards^2)body of water two meters in depth. EFED believes that a body of water of this size represents a very important habitat resource for fish, aquatic invertebrates, and other wildlife. Such ponds are also important as recreational resources for fishing, hunting, and non-consumptive uses of wildlife. In addition, these ponds may be of commercial importance due to their potential use for aquaculture and irrigation. The 1-hectare pond is conservative when compared to many aquatic environments including most rivers, streams, lakes, reservoirs, and large wetlands. However, it is not intended to be a "worst-case" scenario and is not conservative in comparison with other surface waters such as vernal pools and wetlands, where water volumes are less than the pond scenario, turnover may be extremely limited, and evaporation may serve to concentrate contaminants with time. EFED has encountered a number of cases where monitoring data for ecologically important surface water were in excess of concentrations predicted by the 1-hectare pond scenario. In addition, EFED conducted a comparison of contaminant predictions for the farm pond scenario and an index reservoir of larger surface area, volume, and drainage area for presentation to the July, 1998 SAP. Predicted concentrations of hypothetical uses of selected pesticides were higher in the index reservoir than in the 1-hectare pond.

A field dissipation rate is the result of a combination of numerous degradation and dissipation pathways in an actual field environment. EFED's current tools for modeling the fate of a chemical post field application consider the contribution of a number of individual degradation and dissipation pathways. Valid field dissipation data are used in risk characterization and to evaluate the predicted chemical dissipation rates and degradation products. To substitute a field dissipation half-life for soil metabolism as an input parameter would have the erroneous effect of "double counting" many of the other dissipation and degradation pathways.

EFED agrees with JS&C that the use of a 3-day half life for the aerobic soil metabolism input is conservative. This half life value was chosen to represent an upper bound value; however, the 3-day half life is hardly a worst-case input. Ten reports of soil half lives are reported in the risk assessment. The Handbook of Environmental Fate and Exposure Data for Organic Chemicals 1991 states the reported average literature value as 6 days, although the editors fail to cite the literature to which they are referring. In modeling malathion fate and transport in cotton, USDA (1991) also used a conservative 3-day input. The justification given by USDA for using this value was a personal communication with the registrant. Other open literature values suggest that JS&C's suggested 0.2-day or 0.6-day values would adequately represent many scenarios where degradation is favored, but given the wide use of malathion, it is expected that malathion will frequently be used in areas where persistence is likely to be greater. Based on published studies, malathion would be expected to have greater persistence on soils with the following characteristics: low moisture, low organic content, low nitrogen, and increased acidity.

JS&C states that the risk assessment should include aquatic concentration results representing more typical values. The risk assessment has included data on numerous field measurements of malathion in run-off water. These results show very low malathion concentrations and should address JS&C's concern. The field run-off results help to confirm EFED's overall identification

of relative risk: in general, the greatest risks from using malathion are from urban run-off and spray drift. Generally, urban run-off is of greater risk to aquatic resources than agricultural run-off and spray drift, particularly from ULV applications, also poses significant risks to aquatic organisms.

16. **Cheminova comment:** JS&C (page 63) states that a median LC50 value (70 ppb) determined from bluegill toxicity data would be a better tier 1 toxicity endpoint because it would be more representative of malathion toxicity to bluegill, and would take into account some uncertainty surrounding the sensitivity of this species.

EFED response: In general, EFED's policy has been to use the most sensitive species and endpoint from the existing data to insure protection of more sensitive untested species (perhaps sticklebacks in the case of malathion). EFED agrees that the data from test observation #60 (Mayer and Ellersieck) is at higher temperature than normally used and would agree to use of the 30 ppb LC50 obtained in test # 61. However, the most sensitive test result was obtained with the rainbow trout (LC50 = 4.4 ppb) under acceptable conditions of pH, temperature, and hardness (test # 38) and use of this value would greatly change the estimates of risk by a 4 fold increase in risk quotients. Use of mean LC50 values is an approach that may be more representative for that species under a multitude of conditions and age/size ranges, but also may or may not be as protective for other species. In addition, most of the test data were obtained from sources other than Cheminova and many were conducted under static conditions with nominal concentrations used for LC50 calculations. Given malathion's rapid degradation characteristics, this could conceivably lead to higher LC50 values than might have been obtained under flowthrough conditions with measured values.

17. **Cheminova comment:** JS&C states (page 64) that EFED has incorrectly characterized acute risk to aquatic invertebrates by calculating RQs only using daphnid toxicity values.

EFED response: In general, EFED's policy has been to use the most sensitive species and endpoint from the existing data to insure protection of more sensitive untested species and phyla. In general, Daphnia magna is the preferred species; but in the case of malathion, Gammarus fasciatus and Simocephalus serrulatus were more sensitive and would have yielded higher risk quotients. EFED has not routinely conducted analysis of risk for every invertebrate phylum as most chemicals do not have adequate data sets. EFED does turn to toxicity data for a specific phylum in attempting to refine hazard to endangered species.

18. **Cheminova comment:** JS&C (page 64) states EFED has acceptable toxicity data for mollusks, and should calculate separate RQ values for representatives of this phylum.

EFED response: EFED does not routinely calculate separate risk quotients for mollusks, though

for many chemicals where estuarine exposure is expected, the registrant is asked to submit oyster toxicity data. In the discussions regarding protection of endangered mollusks the oyster data are employed to indicate that molluscs may not be of as great a concern:

> "Endangered species LOCs are exceeded for malathion for acute hazard to endangered fish, aquatic invertebrates (with possible exception of molluscs), and insects for most outdoor uses."

19. **Cheminova comment:** JS&C (page 64) states that a number of the aquatic insect species for which EFED presents toxicity data, and expresses concern about, are actually benthic species, and risks to these organisms should not be based on water column EECs. Potential risk to these organisms is more appropriately evaluated using either sediment or pore water EECs.

EFED response: Though EFED has expressed a concern for potential acute toxicity to insect larvae and subsequently emerging adults, there has been no attempt to specifically characterize risk to these groups. As to which exposure compartment (water column or interstitial water concentrations) should be compared, should such an attempt be made for malathion, EFED would be open to discussion on this point. Another point that could be considered is that these larvae may also be located in lentic or lotic habitats which introduces other factors (such as exposure duration and dilution potential) to consider in exposure determination.

20. **Cheminova comment:** JS&C states (page 64) that EFED draws a blanket conclusion concerning potential effects to endangered invertebrates based on RQ values calculated using daphnid toxicity data. For example, the acute toxicity of malathion to unionid mussels, of which many species are endangered or threatened, ranges from moderately toxic (7 mg/L) to practically nontoxic (>350 mg/L) (Keller and Ruessler, 1997); these toxicity values are well above EFED's very conservative EECs.

EFED response: The conclusions stated in the risk conclusions regarding aquatic invertebrates are based on a relatively crude initial screen and LOC based on a sensitive tested species. It should not be construed to apply to every phylum. However, data adequate to characterize risk to all species types expected to be exposed do not exist for malathion (or many other chemicals for that matter). Hazard determination in relation to individual endangered species groups will be further refined by OPP's Endangered Species Branch and this will involve comparison of the appropriate phyla (when data are available) to the species of concern.

21. **Cheminova comment:** JS&C (page 64) requests that EFED provide complete copies of its fish incident reports to Cheminova for review and evaluation.

EFED response: EFED will provide copies of cited incidents, though incidents cited in conjunction with USDA uses are available in the boll weevil and medfly monitoring reports for

that year and location.

22. **Cheminova comment:** JS&C (page 64) questions the rationale for using data developed on vertebrates to justify chronic toxicity testing with invertebrates whose reproductive physiology is completely different from vertebrate physiology.

EFED response: Under fish early life stage and aquatic invertebrate life-cycle, the Code of Federal Regulations (CFR) states "Data from fish early life-stage tests or life cycle tests with aquatic invertebrates (on whichever is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if ... studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected...." CFR does not specify what type of organism must be used to identify the potential life-cycle toxicity. The other criteria stated in the risk assessment and CFR that trigger this requirement are "...LC50 or EC50 value determined in acute toxicity testing is less than 1 mg/l...." and the EEC "... in water is equal to or greater than 0.01 of any EC50 or LC50 determined in acute toxicity testing." Thus malathion triggers the requirement for aquatic invertebrate life-cycle studies for multiple reasons.

23. **Cheminova comment:** JS&C (page 64) states EFED has misrepresented the results of the rainbow trout early lifestage study (Cohle 1989) as indicating a NOEC of 2 ppb. The NOEC from this study was 21 ppb, with a LOEC of 44 ppb (LOEC correctly presented in the RED chapter) and a point estimate MATC of 30.4 ppb. EFED's order of magnitude error on this NOEC has a significant impact on both the chronic RQ calculations and the interpretation of potential chronic risk.

EFED response: The noted toxicity value for rainbow trout in the risk assessment was incorrect. The NOEC for fry survival and swimup, was 21 not 2 ppb. Review of American Cyanamid's study report confirms this point. EFED has corrected the reported value in the risk assessment and recalculated risk quotients using the correct value. Although the corrected value suggests a lower risk for trout, the NOEC for sheepshead minnow may be as low as 4 ppb (Parrish, Patrick R., 1977- EPA-600/3-77-059). These data suggest that while rainbow trout are not be the most sensitive fish species, some fish species are still expected to be affected at low malathion concentrations.

24. **Cheminova comment:** JS&C states (page 64) that they disagree with EFED's conclusions concerning the potential for chronic risk to either fish or aquatic invertebrates given the rapid degradation of malathion in natural water bodies. Both modeling and monitoring data indicate that aquatic organisms are most likely to be exposed to acute pulses of malathion that dissipate within days rather than continuous exposures at relatively constant concentrations. Therefore, Cheminova questions the relevance of chronic risk evaluations based on standard longer-term toxicity testing that involves

continuous exposure to constant test concentrations for 21 days (daphnids) to 90-95 days (trout early life stage).

EFED response: EFED agrees with JS&C that under most condition malathion is not persistent. The risk assessment clearly defines malathion persistence in both modeled and monitored water bodies. However, given malathion's wide and frequent use, EFED believes that multiple pulsed loads of malathion to water bodies are likely to occur which would result in chronic exposure (see page 110 under "Risks to Fish" where chronic risk potential is discussed). In addition, the results of chronic toxicity studies do not indicate how short exposure can be and still result in toxicity. Toxicity endpoints identified in chronic studies may result from non-continuos exposures.

25. Cheminova comment: JS&C (page 65) states that the information included in the RED chapter on monitoring of mosquito applications indicates much lower concentrations than some of those presented for the Medfly monitoring, indicating that Medfly monitoring data are not a good surrogate for mosquito applications. The Medfly modeling certainly is inappropriate for assessing the risk from agricultural applications.

EFED response: Medfly application modeling or monitoring was not used for assessing the risk from agricultural applications, it was used to qualitatively assess the risk associated urban uses of malathion including mosquito control. EFED agrees with JS&C that the formulations used for mosquito adulticide applications are different from medfly applications which are mixed with a bait, but does not believe these differences affect the conclusions reached in the assessment. Mosquito applications are intentionally applied with very small drops which drift long distances and are effective in contacting and knocking down flying mosquitoes. The medfly applications are applied with larger drops containing fruit fly bait and do not drift as far. EFED does not believe that the formulation differences between medfly and mosquito applications would make a significant difference in the environmental fate or runoff potential of malathion in urban environments. The increased drift of mosquito adulticide applications may result in higher aquatic concentrations due to deposition into water bodies relative to medfly applications which are less drift-prone and typically employ no-spray zones around the water bodies. EFED has made no attempt to use medfly modeling in calculating aquatic risk quotients. Attempts to look at ingestion of baits simply support the conclusion that there is only very low risk to terrestrial vertebrates as a result of this use.

26. Cheminova comment: JS&C states (page 65) "...that is notable that most of the contribution to the EECs for the monitoring data presented by EFED is from spray drift, while EFED's models predict that most of the contribution comes from runoff. There are likely two reasons for this discrepancy. First, the Medfly programs result in higher spray drift loading of malathion to water bodies relative to agricultural applications. Second, EFED's models likely significantly overestimate runoff contributions because it is very rare for an agricultural field to be right at the edge of a water body and because EFED

assumes exaggerated worst-case values for all model input parameters, resulting in exagerrated estimates of runoff loading."

EFED response: Partially agrees with JS&C. EFED agrees that monitoring data from agricultural applications suggest that spray drift results in higher levels in water bodies than runoff. However JS&C has focused on medfly applications. EFED does not believe and does not state in the risk assessment that drift from medfly applications is in any way representative of drift from agricultural applications. EFED has identified aerial agricultural ULV applications as being high risk. Measured downwind deposition from malathion ULV applications under conditions appropriate for spraying cotton presents serious risk to aquatic organisms. In regard to runoff contributions, EFED does not believe the inputs used in modeling malathion runoff were "exaggerated worst-case". However, it is likely that the model inputs were not appropriate to the monitored sites. One must be careful in comparing model results and monitored values accounting for the application rate, frequency of application, timing with rain events, and the duration of sampling (PRZM/EXAMS is typically run over a 30-year period).

27. Cheminova comment: In regard to table 37 (High exposure scenario EECs and RQs Direct Application to Water or 100% Drift) in the risk assessment, JS&C (page 66) states that EFED's calculations assume that malathion spray drift loadings to these water bodies are instantaneously and homogeneously mixed through the water column. Also, EFED made no attempt to account for environmental fate degradation in these calculations. Thus, any RQs calculated with these EECs represent only crude screening-level values, and should not be used to imply that significant risk exists.

EFED response: As JS&C states the EECs and RQs calculated in this table are intended as screening level values, however, this does not imply that in all instances they are extremely conservative. The calculated values are a screen based on direct contact to water with no runoff contribution. They were used only for acute risk level estimates. Contrary to JS&C's statement that most water bodies are deeper than 6 feet (page 66) and only rarely immediately adjacent to agricultural land (page 65), a large number of water bodies are shallower than 6 feet and immediately adjacent to agricultural land. Since no-spray zones are not currently included on malathion labels, malathion applications can result indirect deposition to water bodies including lakes, ponds, reservoirs, permanently flooded areas, and swamps, marshes, and wetlands.

28. Cheminova comment: Because there is no mention of the critical role that malathion spraying plays in human disease prevention in some urban areas, JS&C believes that this discussion presented in the risk assessment misinforms the public as to malathion's benefits in controlling vectors of disease.

EFED response: EFED has revised the risk assessment and added the disease control example cited by JS&C as follows:

Summary of Public Health Uses

Mosquito control in populated and rural areas comprises the major use of malathion for public health uses. In general, public health use would be necessitated by actual or potential disease outbreak caused by a particular pest. A recent example was the 1999 West Nile Virus spraying program implemented by New York. Though mosquito control does potentially prevent such outbreaks (particularly after hurricanes or major storms) much of the application is also performed when a disease problem has not been documented. In some areas, numerous public complaints to local mosquito control officials may be adequate incentive to implement spraying operations. This type of use is particularly heavy near coastal resort areas, where high bite rates constitute a potential loss of tourist revenue and therefore an incentive for active spraying programs. High use of adulticides is generally an indication that larvicidal uses of pesticides during the early breeding season have failed to control population outbreaks.

29. **Cheminova comment:** JS&C states that the risk assessment for cotton is based on application scenarios for the boll weevil eradication program, which are not representative of other agricultural uses of malathion on cotton. JS&C believes EFED should either conduct a separate risk assessment for non-boll weevil eradication uses on cotton, or clearly indicate that its assessment for cotton only applies to the boll weevil program. JS&C states that the risk assessment implies that a buffer zone may be appropriate for the boll weevil eradication program.

EFED response: Rates, methods, and in some cases frequency of application are not unique to boll weevil control as similar scenarios are permitted for other crops as well as cotton on malathion labels [see table 2 for EC suggested label rates for cotton in the Cheminova response and EFED table regarding other crops listed for 2.5 lb ai/A (figs, nut crops, and peas)]. Any references regarding buffer zones are for protection of non-target aquatic resources and not a comment on what is most effective for achieving boll weevil control. Based on the detailed monitoring reports provided by USDA, EFED believes the boll weevil program has exercised a great deal of caution in its use of malathion for boll weevil eradication and that boll weevil eradication would lead to significantly reduced usage of insecticides on cotton.

30. **Cheminova comment:** JS&C states (page 67) that the RED chapter mixes Medfly control, mosquito control, and homeowner/residential uses under the residential and urban use heading. JS&C believes that differences associated with each of these use patterns (e.g. formulations, application equipment, application method, and rate) necessitate separating these uses for risk assessment purposes.

EFED response: EFED is very fortunate to have monitoring data for malathion in urban settings. Both USGS and USDA monitoring data collected in urban areas greatly helped to identify the

risks associated with urban use relative to agricultural use. Monitoring data from both sources suggested that malathion occurs more frequently and at higher levels in urban environments. Based on the results of the studies and a review of the chemistry of malathion, EFED concluded that malathion contacting impermeable surfaces is more likely to persist, convert to malaoxon, run-off, and contaminate surface water bodies. EFED believes the risk from urban malathion usage to surface water could be reduced by minimizing the amount of malathion that contacts anthropogenic surfaces. Some of the differences between uses listed by JS&C (application equipment, application method, and rate) are expected to affect the amount of malathion contacting these surfaces (also see response 24 above). However, the fate and transport (run-off) of malathion after contacting surfaces are not affected by the differences listed by JS&C. The monitoring data provide a very strong basis for focusing on risks of urban malathion use. EFED agrees with JS&C that individual urban uses should be scrutinized to identify those with the highest potential to contact impermeable surfaces, however, end result monitoring (as was conducted by USGS) does not distinguish between sources.

31. **Cheminova comment:** JS&C states (page 71): "EFED's discussion of the bobwhite quail reproduction study (Beavers et al 1995) has misstated the results of that study. First, quail were exposed to continuous dietary concentrations of 0 (control), 110 ppm, 350 ppm, or 1200 ppm malathion for 21 weeks, not 10 weeks as described by EFED. Secondly, the NOEC cited by EFED (110 ppm) represents a chronic toxicity NOEC, not a NOEC for reproductive performance. Furthermore, this chronic NOEC was not determined using rigorous statistical methods, rather it represents the conducting laboratory's impression that necropsy results for a few birds indicated a possible chronic effect at 350 ppm. Statistical analysis of each of these test endpoints (regressed/regresssing ovaries and flaccid/enlarged gizzards) indicates no statistically significant difference between the control and 350 ppm groups using the Fischer's exact Test, so the NOEC for these effects is also 350 ppm. The NOEC for reproductive performance, based on statistical analysis, was 350 ppm, and this is the value that should be used for evaluating potential reproductive risks. Finally, EFED mischaracterized the effects that occurred at the 1200 ppm test concentration by implying that only effects on reproductive performance occurred, when actually significant parental toxicity occurred at this concentration, including weight loss, reduced feed consumption, clinical signs of toxicity, and mortality. All the effects on reproductive performance, including thinner eggshells, at this concentration are clearly secondary to the significant parental toxicity that occurred at this test concentration, and EFED's discussion should so indicate.

"Cheminova disagrees with EFED's statement that the effects noted at 350 ppm and above in the quail reproduction study were reduced egghatch and regressed ovaries which could indicate that early exposure to malathion may have lead to the observed effects. As explained above, there were no statistically significant effects on reproductive performance at 350 ppm, and there is no correlation between the reproductive performance of individual birds (e.g., eggs laid, viability, hatchability) and those few birds that the testing

laboratory believed showed signs of regressing ovaries at this concentration at study termination. At the 1200 ppm test concentration, early (short-term) exposure to malathion initially resulted in body weight loss and clinical signs of toxicity to parental birds; these effects were noted in some individual birds in the second week of the study and any effects on reproductive parameters are secondary to these initial effects of parental toxicity."

EFED response: EFED has corrected the text to reflect the correct duration of exposure. The observations of regressed ovaries were observed in enough of the treatment birds to be considered an effect of the treatment - regressed ovaries were not reported in the control birds. The study author, who has much experience in conducting toxicity studies, identified an effect at 350 ppm. In the absence of data contradicting this result EFED supports the author's conclusion.

Even though the Agency is not in complete agreement with JS&C's statement, it should be noted that levels of concern for chronic risk would still be exceeded by labeled malathion uses if the endpoints were modified as suggested by JS&C. The single application risk levels would begin at higher levels of application, but within the median application rates for malathion. In addition, nesting birds are expected to potentially receive repeated exposures from multiple applications.

32. Cheminova comment: JS&C states (page 72): "EFED's discussion of potential adverse effects from sublethal exposures of nontarget organisms to malathion, particularly in the summary section of its RED chapter, is highly speculative, implying that a wide range of sublethal effects routinely occur with malathion use. However, this discussion neither relates dose to sublethal effects, nor does it provide data on potential exposures relative to doses that can in EPA's view cause adverse sublethal effects. In fact, despite EFED's attempts to portray malathion otherwise, most of the field data cited in this RED chapter and additional literature not referenced by EFED (e.g., Bejer-Petersen et al, 1972; Joseph, 1972; Mclean et al, 1975; Pascual, 1994; Webber 1991), indicate minimal or no adverse effects on a majority of terrestrial species monitored under a variety of malathion use scenarios.

"The study by Mehrotra et al (1966) on sparrows is not a field study and should be moved to the "non-guideline laboratory studies" section of the RED chapter."

EFED response: Malathion is an acetylcholinesterase inhibitor and sublethal effects associated with organophosphate insecticides with this mode of action are very well documented. EFED agrees that the most serious effects resulting from malathion use are on non-target insects and aquatic organisms, and not to mammals or birds. However, EFED is not certain that malathion is innocuous to birds, or to other vertebrate groups for that matter. Chemicals affecting the nervous system can greatly affect an animals ability to forage, nest, and evade predators.

This section related to the non-guideline studies has been revised.

33. **Cheminova comment:** JS&C states (page 72) "The Fish and Wildlife Service (FWS) toxicity data on aquatic larval stages of terrestrial insects are inappropriately described by EFED. These studies are all standard acute toxicity studies conducted similarly to acute toxicity studies on other routinely-tested aquatic invertebrate species (e.g., daphnids). As such, it is inappropriate for EFED to claim that these studies indicate that population effects may occur under field-use conditions (particularly when field data indicate that insect species, if affected, recover quickly)."

EFED response: If the organisms die before maturity it would is likely that a local population effect would occur. In addition, other studies cited in the review do show temporary reductions in some taxonomic groups.

34. **Cheminova comment:** JS&C states (page 73) that data are presented in the EFED risk assessment which show that malathion is highly toxic to bees in the laboratory. JS&C states they believe in the acute toxicity studies, bees are confined to cages containing chopped leaves from plants that have been sprayed with the test compound. JS&C believes this test design produces results that are unrepresentative of the field situation as a result of the unrealistically high exposure and, in the case of honeybees, data on the duration of residual toxicity is of very limited value.

EFED response: EFED is open to discussion regarding methodology options for non-target insect testing protocols. However, the cited field data were not restricted to honeybees confined to cages. At this time EFED dose not perform an risk assessment on non-target insects.

35. **Cheminova Comment:** JS&C (page 73) believes that the following items are underlying assumptions of avian and mammalian acute and chronic risk assessments.

1. One hundred percent of a crop is assumed to be treated with the product being evaluated.
2. Birds and mammals are assumed to ingest only treated feed items over the entire duration of exposure.
3. Birds and mammals are assumed to ingest only feed items containing the maximum day 0 estimated residues over the duration of the exposure period.
4. For acute risk, no degradation of residues occurs on the feed items during the exposure period.
5. A bird's or mammal's diet consists only of items from one of EFED's feed item categories throughout the exposure period.
6. All birds and mammals are as sensitive to a chemical as the most sensitive species tested, even in cases where an extensive database exists on a variety of species,

showing substantial variability in susceptibility.

EFED response: EFED believes, as JS&C states, that all assumptions made for the risk assessment should be specified, however, EFED believes the items outlined by JS&C are not accurate representations of the assumption made in the risk assessment.
The Agency is aware of the fact that certain assumptions are made in our risk assessment process which may contribute to a certain level of margin protection. On the other hand, use of limited data sets such as those required of registrants may also contribute to under-protection of species more sensitive than the test species or to organisms living in habitats which are already stressed by other contaminant loads or subject to larger watershed contributions than already used in model predictions among other points.

Comments are provided for the individual points.

1. The Agency has not received data to characterize the percent of the crop area for each crop that is treated, however, many animals have small ranges. Thus, individuals dependent on resources in a confined area are unaffected by how much of the national crop is treated. The percentage of crop treated is irrelevant for this type of assessment.

2. The agency is unaware of any database that would completely characterize the diet ingestion potential of all exposed organisms over time. There are some limited literature sources on this type of ingestion data for certain species.

3. For multiple applications - half-life values are employed to degrade the initial dose before the second application. Day 0 values are used for acute exposures only, though it could be argued that organisms may or may not consume the items on that particular date.

4. This comment is not true for multiple application scenarios. Degradation is estimated on food items.

5. EFED assumes that certain types of food preferences will influence which organisms are most likely to be affected, and this generally should be discussed in the risk characterization if hazard is predicted for that group of organisms. In expressing risk quotients for this RED, EFED employed ranges of risk quotients which may or may not include levels of exceedance-depending on the percent of that diet item which predominates in normal daily intake.

6. Registrant-submitted data on two bird species are used to estimate risk to all birds existing the chemical's use area. For a widely used chemical like malathion, more than a hundred bird species may be exposed to residues. EFED uses the most sensitive species for quantitative estimates of risk because it is likely that more sensitive species exist in the area of exposure.

36. **Cheminova comment:** JS&C (page 74) states that recent analysis of the UTAB database that serves as the basis of EFED's estimated residues on avian and mammalian feed items indicates that EFED's estimated residue values for short grass (240 ppm/lb a.i. applied) and long grass (110 ppm/lb a.i. applied) are greater than the 99th percentile of residues for these categories in the UTAB database. JS&C also states that EFED's estimated residue value for forage and leafy crops (135 ppm/lb a.i. applied) represents approximately the 95th percentile, and EFED's estimated residue for fruits and seeds (15 ppm/lb a.i. applied) represents the 98th percentile.

EFED response: EFED believes that a discussion of the validity of the use of Kenaga nomograph values, as modified by Fletcher et al. must recognize that the values are based on a robust set of actual field residue data. Hoerger and Kenaga (1972) state that the upper limit values from the nomograph represent the 95th percentile of residue values from actual field measurements. The Fletcher et al. (1994) modifications to the Kenaga nomograph are also based on measured field residues from 249 published research papers, including information on 118 species of plants, 121 pesticides, and 17 chemical classes. These modifications represent the 95th percentile of the expanded data set.

Because pesticide regulatory decisions involve potentially widespread uses of pesticides, EFED believes that the use of upper limit values is necessary to account for the potential variability and uncertainty associated with application to a wide variety of use sites under a variety of environmental conditions. However, EFED is open to alternate analyses of this and other chemical-specific data. Unless such data are submitted, EFED will continue to use the Kenaga nomograph values, as modified by Fletcher et al.

37. **Cheminova comment:** JS&C states (page 76): "As discussed above, EFED's risk quotient calculations for potential reproductive risk to birds use the wrong toxicity endpoint. Results of the quail reproduction study that EFED uses for selecting a NOEC to use in longer-term chronic avian risk assessment indicate that the NOEC for effects on reproductive performance is 350 ppm, not the 110 ppm value EFED is using in its assessment. Use of a toxicity endpoint that is a factor of three is too low, and obviously has a significant impact on both RQ calculations and interpretation of potential risk."

EFED response: See response to comment 31 above.

38. **Cheminova comments:** JS&C (page 76) states: "The acute avian dietary risk quotients presented in Table 30 of the draft RED do not support EFED's interpretation that single broadcast applications of malathion exceed the acute high risk, restricted-use, and endangered species LOCs at application rates of 3.75, 2.0, and 0.94 lb a.i./acre, respectively. EFED's calculated RQs for single application rates of 3.75 lb a.i./acre range from 0.01-0.34; EFED's calculated RQs for a single application at 2.0 lb a.i./acre range

from 0.005-0.18; and EFED's calculated RQs for a single application at 0.94 lb a.i./acre range from 0.002-0.08. All of these values are below the applicable LOCs."

EFED response: Please refer to the multiple application RQ's for these application rates. The RQ s listed above are for single applications only. Multiple application RQ ranges were 0.58 to 0.04, 0.34-0.02, and 0.15-0.01 respectively. The text associated with table 30 has been modified to better reflect this.

Response to "Comments from the US Department of Agriculture Animal and Plant Health Inspection Service on EPA's Preliminary Risk Assessments for Malathion" July 10, 2000, U.S. Department of Agriculture, Animal Plant Inspection Service.

USDA comment: USDA (page 8) questions EFED request of an aerobic aquatic malathion study under acidic conditions. USDA states that it has provided EPA with six years of environmental monitoring data with natural water bodies in which the pH was neutral or acidic.

EFED response: EFED confirms that it has received a wealth of monitoring data from the USDA on the environmental fate and persistence of malathion under a wide range of conditions. The data which USDA provided have generally been of very high quality and invaluable in performing the malathion risk assessment. Although the USDA provides data on the persistence malathion in natural water bodies the data are not collected under controlled conditions and do not allow a decline curve to be calculated. Typically, the USDA data show detections in static water bodies slightly above the level of quantitation. In the subsequent samples, malathion is below the level of quantitation or the detection level. More useful data on malathion degradation would have measurements made at enough time point to generate a decline curve and determine the order of the kinetics involved.

It should be noted that USDA states that data were collected in a large number of neutral to acidic ponds, rivers, and streams. This statement stands in contrast to JS&C's statement (page 56) that alkaline pHs are more typical of natural water bodies. Neutral to acidic water bodies do commonly exist as documented by USDA.

USDA comment: USDA (page 8) states EPA has requested data on malathion conversion to malaoxon under anaerobic conditions. USDA states oxidation of malathion will not occur under anaerobic conditions and therefore malaoxon production will not occur.

EFED response: EFED agrees with USDA's statement that oxidation of malathion will not occur under anaerobic conditions, however, EFED is not aware of making the request that USDA is

claiming. On page 5 of the cover memo for the risk assessment EFED states:

> "...EFED believes that hydrolysis data along with open literature data on the persistence of malathion in sediments is sufficient to conclude that malathion will not persist under anaerobic conditions and therefore a repeat of this study is not required at this time."

Also, on page 22 of the risk assessment EFED states:

> "[the anaerobic aquatic metabolism study] is considered satisfactory with supporting hydrolysis and open literature data suggesting that malathion is unlikely to persist in anaerobic aquatic conditions (MRID 42216301, 43166301). Repeated studies under acidic conditions may be requested if more quantitative data on malathion persistence in these environments are required."

USDA also notes on page 9 that: "EFED further states that if conditions become anaerobic, the oxidative breakdown of malathion to malaoxon will not occur due to the lack of oxygen." USDA's criticism appears to be contradictory to statements made in their own comments. EFED is not aware of the unreferenced request for additional data under anaerobic conditions or any suggestion that malaoxon production is likely to occur under anaerobic conditions.

USDA comment: USDA (page 9)states that the screening level drinking water concentrations supplied to the Health Effects Division were unrealistic. USDA states: "No circumstances exist that would result in concentrations of malathion at 21 ppb or malaoxon at 75 ppb over extended periods."

EFED response: Please see the above response to JS&C's second comment.

USDA comment: USDA (page 9) criticizes EFED's estimate of drinking water concentrations stating: "APHIS believes that EFED's statements are erroneous because aquifer recharge areas comprised of dry abiotic surfaces are either rare or nonexistent. Therefore, there is no chance that a drinking water well will be recharged from a watershed comprised of dry abiotic surfaces and hence there will be no malaoxon in the drinking water."

EFED response: USDA has assumed that the statements in the risk assessment related to dry, abiotic surfaces apply to ground water contamination. In the risk assessment the statements are made in relation only to surface water measurements. Many watersheds providing water to lakes, rivers, and reservoirs providing drinking water are comprised in part by these types of surfaces. In general, watersheds with higher levels of urbanization have higher percentages of impermeable surfaces. Western states' watersheds experience highly seasonal periods of rain and are dry much of the year. The statements in the risk assessment referring to dry and abiotic surfaces are associated with surface water and runoff. It is not apparent what part(s) of the risk assessment

resulted in USDA's misinterpretation.

USDA comment: USDA states (page 9) that many aquatic organisms, including most fish, are highly tolerant to malathion.

EFED response: EFED disagrees with USDA's comment and believes most fish and invertebrates are sensitive to malathion at concentrations in the part-per-billion range in laboratory settings.

USDA comment: USDA states (page 10) "Adverse effects of malathion on the development of birds were observed only when it was injected directly into fertilized eggs at concentrations not likely to result under any other conditions. It should be noted that the studies cited by EFED that involved the injection of malathion into fertilized eggs are all more than 30 years old. This technique is seldom used today to assess reproductive effects, and EPA lists these studies as 'Non-Guideline Laboratory Studies.'"

EFED response: EFED believes the following study information on quail contradict USDA's statement: Quail were exposed to continuous dietary concentrations of 0 (control), 110 ppm, 350 ppm, or 1200 ppm malathion for 21 weeks. The NOEC cited by EFED (110 ppm) represents a chronic toxicity NOEC, not a NOEC for reproductive performance. The observations of regressed ovaries were observed in enough of the treatment birds to be considered an effect of the treatment - regressed ovaries were not reported in the control birds.

USDA comment: USDA states (page 11) "...APHIS' environmental monitoring program has concluded that none of the few bird and mammal mortalities reported during Medfly or Boll Weevil treatment activities was due to malathion toxicity. The Ecological Risk Characterization, Risk to Terrestrial Vertebrates section in the EFED Preliminary Risk Assessment should be revised to indicate that no field studies to date show a significant effect on the health of wild birds."

EFED response: EFED would agree that acute toxicity effects are unlikely from USDA program usage of malathion. EFED also does not believe that adequate monitoring research has been done to characterize the total potential effects to birds from continous exposure to birds. With effects definitely observed at 350 ppm and potentially at 110 ppm in bobwhite reproduction studies, this point needs to be further investigated.

References

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